UNIVERSITY OF

ROCHESTER

MEDICAL CENTER

TRANSFUSION MEDICINE UNIT AND
BLOOD BANK
BOX 608
601 ELMWOOD AVENUE
ROCHESTER, NEW YORK 14642
(USA)

STRONG MEMORIAL HOSPITAL
SCHOOL OF MEDICINE AND DENTISTRY
DEPARTMENT OF PATHOLOGY
AND LABORATORY MEDICINE

Neil Blumberg MD, Medical Director
Scott A. Kirkley MD, Assistant Medical Director

TELEPHONE: 716 / 275-3189 or 275-2251
FAX: 716 / 473-6886 or 273-1027
e-mail: Neil_Blumberg@urmc.rochester.edu

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December 13, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To whom it may concern:

This comment on the proposed rule 21 CFR Parts 607, 610, 640, and 660 [Docket No. 98N-0581] "Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents" specifically responds to the question of whether requiring testing for infectious disease markers is efficacious and appropriate for use on autologous donor units. I comment based upon about 25 years experience in transfusion medicine and 20 years as the medical director of a tertiary care university hospital blood bank.

The proposed testing requirement for autologous donations, while well intended, will have no benefit for patients, either the donor, or the potential incorrect, unintended recipient. There are no data to support the contention that testing of units intended ONLY for autologous use will reduce the risk of mis-transfusion in the slightest. Indeed, the only certain effect will be to increase the cost of autologous transfusion, a risk reducing and cost saving procedure, by at least $25 per unit (amounting to $25,000 in additional needless expense in our institution, and millions of dollars nationwide). Given the almost certain lack of clinical utility of testing blood intended solely for reinfusion to the donor, these costs are unwarranted and will divert limited health care funds from other worthwhile uses.

The requirement for testing of autologous blood probably will have the unintended consequence of injuring some patients who could benefit from this modality of therapy. Some physicians will refuse to accept donated units with positive tests, even though in our experience most of these results are false positives on further

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testing. Some physicians misguidedly will decide not to let HIV or hepatitis C positive patients donate, thus violating the Americans with Disability Act which provides for equal treatment regardless of patient illness or disability. Since there is evidence that autologous donation and transfusion not only reduces the immunologic and infectious risks of transfusion, but mitigates immunomodulatory effects that prolong length of hospital stay and increase morbidity and mortality, denial of autologous procedures due to positive infectious disease tests paradoxically will contribute to increased risks for patients.

An alternative approach that I would suggest for consideration, based upon our policies,is as follows. Rule that autologous donations can only be used for the donor, and label such units prominently and uniquely as "autologous use only." In our hospital we collect autologous units into bags labeled quite distinctly with whole bag green labels that easily distinguish them from fully tested allogeneic volunteer donor blood with their white labels. Thus far, the error rate for administration to the wrong recipient of autologous units so labeled is zero out of perhaps 10-15,000 transfusions. Had we tested such units for infectious disease markers it would in no way have decreased the likelihood of mis-transfusion. Indeed, labeling fully tested autologous units in a similar fashion to allogeneic tested units undoubtedly will carry significantly greater risk than the approach I have outlined.

In summary, I suggest that there be no required infectious disease testing for units designated for autologous reinfusion only, that unique labeling in color and design for autologous units be required, and that such units be prominently labeled or tagged with the donor's name, and and that "crossover" of autologous units for allogeneic use be forbidden. This will be more effective and safer without doubt, and certainly enormously less expensive than the strategy of requiring infectious disease testing. Thanks very much for your time and attention.

Sincerely,

Neil Blumberg

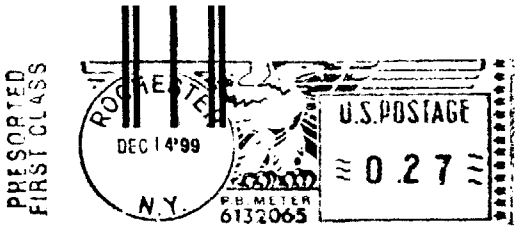
Neil Blumberg MD
Professor of Pathology and
Laboratory Medicine
Director, Transfusion Medicine/Blood
Bank

UNIVERSITY OF
ROCHESTER
MEDICAL CENTER

601 Elmwood Avenue
Rochester, New York 14642

[USA]

Neil Blumberg MD, Box 608



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